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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	4

DATE MAILED: 09/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/809,062	Applicant(s) PATZKE, JURGEN	
	Examiner Maureen M. Wallenhorst	Art Unit 1743	

-- Th MAILING DATE of this communication app ars on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 18-44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 18-44 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. The disclosure is objected to because of the following informalities: Applicant is requested to provide headings in the specification for the "Background of the Invention", the "Summary of the Invention", the "Brief Description of the Drawings" and the "Detailed Description". In addition, Applicant is requested to move the brief description of the drawings currently on page 13 of the specification to a location after the summary of the invention.

Appropriate correction is required.

3. Claims 18-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is indefinite since it recites a method for measuring aggregation of blood platelets both in the preamble of the claim and in step d) of the method. However, nowhere in the body of claim 18 does it recite that the sample contains blood platelets. In addition, the reaction mixture ingredients recited in part b) of claim 18 are indefinite since it is not clear whether these reagents cause platelets to aggregate. The function of the reaction mixture ingredients is not clear. See these same problems in claim 28.

In claim 20, the phrase "the stirring rate" lacks antecedent basis. See this same problem in claim 30.

Claim 28 is indefinite since the preamble of the claim recites a method of measuring the stability of blood platelet aggregates. However, the last step of the method does not explain how

this function is performed by comparing the first aggregation measurement to the second aggregation measurement.

In claim 41, the phrase "the remaining unaggregated platelets" lacks antecedent basis, and should be changed to –any remaining unaggregated platelets--.

Claim 43 is indefinite since it is not clear whether all platelets in the methods of claims 18 or 28 are replaced with cells, etc., or whether only some of the platelets are replaced. If all of the platelets are replaced, then the methods of claims 18 and 28 would not be methods of measuring the aggregation of platelets. On line 1 of claim 43, the phrase "may be" is indefinite since it does not constitute a definite, positive limitation, only a possibility.

It is suggested to recite in claim 44 that the mixing in the second reaction phase is of a lower intensity than in the first reaction phase for additional clarification.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 18-21, 24-31, 34-37 and 40-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Longmire et al (submitted in the Information Disclosure Statement filed on March 16, 2001).

Longmire et al teach of a method for measuring platelet aggregation, which comprises the steps of combining a sample of platelet rich plasma (PRP) with the aggregation activator adenosine diphosphate (ADP), stirring the reaction mixture for 0.5 seconds in a first reaction phase, then incubating the reaction mixture in a second reaction phase in a nonstirred condition,

and measuring the resulting aggregation of the platelets. The percent aggregation is computed from the decrease in particle concentration with time measured with a resistive particle counter. Longmire et al teach that in the nonstirred condition, Brownian diffusion causes the platelets to collide with one another to form aggregates. Longmire et al teach that the platelet aggregation resulting from the steps of stirring followed by nonstirring is compared to samples of platelets which undergo aggregation by constant stirring in the presence of ADP. See the abstract, and page 300 of Longmire et al. Platelet aggregation is measured by taking an initial platelet particle count at time 0 before the platelets are stirred for 0.5 seconds followed by nonstirring, and then again at time t after activator addition, stirring and nonstirring.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 22-23 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Longmire et al in view of Kitek et al (submitted in the Information Disclosure Statement filed on March 16, 2001). For a teaching of Longmire et al, see previous paragraphs in this Office action.

Longmire et al fail to teach of measuring platelet aggregation using fixed blood platelets in a ristocetin cofactor test.

Kitek et al teach of a method for measuring platelet aggregation wherein formalin-fixed platelets are combined with ristocetin-cofactor, and the presence of microaggregates is determined by a turbidometric analysis. See page 155 of Kitek et al.

Based upon the combination of Longmire et al and Kitek et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to measure platelet aggregation in the stirring followed by nonstirring method taught by Longmire et al using fixed platelets in a ristocetin-cofactor assay since Kitek et al teach that a common method of evaluating platelet aggregation is to fix platelets and combine with ristocetin-cofactor as an activator of platelet aggregation, and the method disclosed by Longmire et al involves the combination of a platelet sample with an activator of aggregation (i.e. ADP). The substitution of one platelet aggregation activator for another known activator would have been obvious to one of ordinary skill in the art so long as the activators achieve the same function, i.e. the aggregation of platelets.

9. Claims 38-39 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Longmire et al. For a teaching of Longmire et al, see previous paragraphs in this Office action.

Longmire et al fail to teach of sequentially stirring and not stirring the platelet samples in the method of measuring platelet aggregation, and of slowing the stirring down in the second reaction phase rather than completely stopping the stirring. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to adjust the conditions of the platelet aggregation assay taught by Longmire et al to include either sequential

periods of stirring followed by nonstirring or to slowly stir the platelet reaction mixture in the second reaction phase rather than stopping the stirring completely, so as to further evaluate the effect that Brownian diffusion-controlled platelet collisions have on platelet aggregation under different conditions where the Brownian motion of platelets is combined with physically stimulated motion of platelets (i.e. stirring).

10. Claims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Longmire et al in view of Minamoto et al (submitted in the Information Disclosure Statement filed on November 9, 2001). For a teaching of Longmire et al, see previous paragraphs in this Office action. Longmire et al fail to teach of measuring platelet aggregation, wherein platelets are combined with other particles containing ligands or receptors thereon that facilitate aggregation.

Minamoto et al teach of a method for measuring platelet aggregation, which comprises the steps of combining a platelet sample with polystyrene beads coated with von Willebrand factor or fibrinogen, and measuring the aggregation of the platelets and beads using a turbidometric assay. The beads serve as an activator of platelet aggregation.

Based upon the combination of Longmire et al and Minamoto et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to measure platelet aggregation in the stirring followed by nonstirring method taught by Longmire et al using platelets combined with beads having ligands or receptors for platelets bound thereto since Minamoto et al teach that a common method of evaluating platelet aggregation is to combine platelets with particles such as polystyrene beads containing ligands or receptors for platelets thereon as an activator of platelet aggregation, and the method disclosed by Longmire et al involves the combination of a platelet sample with an activator of aggregation (i.e. ADP). The

substitution of one platelet aggregation activator for another known activator would have been obvious to one of ordinary skill in the art so long as the activators achieve the same function, i.e. the aggregation of platelets.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Kleszynski et al and Fratantoni et al who both teach of methods for measuring platelet aggregation.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 2, 2003

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted]700